

## Food and Drug Administration, HHS

## § 524.1600b

deep or puncture wounds or serious burns, use only as recommended by a veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.<sup>1</sup>

[49 FR 9417, Mar. 13, 1984]

### § 524.1600 Nystatin ophthalmic and topical dosage forms.

#### § 524.1600a Nystatin, neomycin, thioestrepton, and triamcinolone acetone ointment.

(a) *Specifications.* Each milliliter of petrolatum base or each gram of vanishing cream base ointment contains: 100,000 units of nystatin; neomycin sulfate equivalent to 2.5 milligrams of neomycin base; 2,500 units of thioestrepton; and 1.0 milligram of triamcinolone acetone.

(b) *Sponsors.* For petrolatum base ointments see 000031, 000069, 000332, 025463, 051259, and 053501 in § 510.600(c) of this chapter. For vanishing cream base ointments see 051259 and 053501.

(c) *Conditions of use*—(1) *Amount.* (i) For topical dermatological use: Clean affected areas and remove any encrusted discharge or exudate, and apply sparingly either ointment in a thin film.

(ii) For otic use: Clean ear canal of impacted cerumen, remove any foreign bodies such as grass awns and ticks, and instill three to five drops of petrolatum base ointment. Preliminary use of a local anesthetic may be advisable.

(iii) For infected anal glands and cystic areas: Drain gland or cyst and fill with petrolatum base ointment.

(2) *Indications for use.* (i) Topically: Use either ointment in dogs and cats for anti-inflammatory, antipruritic, antifungal, and antibacterial treatment of superficial bacterial infections, and for dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal (*Candida albicans*) infections.

(ii) Otitis, cysts, and anal gland infections: Use petrolatum base ointment in dogs and cats for the treatment of acute and chronic otitis and interdigital cysts, and in dogs for anal gland infections.

(3) *Limitations.* For mild inflammations, use once daily to once a week.

For severe conditions, apply initially two to three times daily, decreasing frequency as improvement occurs. Not intended for treatment of deep abscesses or deep-seated infections. Not for ophthalmic use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 43 FR 29770, July 11, 1978; 50 FR 41490, Oct. 11, 1985; 53 FR 39257, Oct. 6, 1988; 54 FR 5431, Feb. 3, 1989; 54 FR 48090, Nov. 21, 1989; 56 FR 50653, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 61 FR 63712, Dec. 2, 1996; 64 FR 42831, Aug. 6, 1999]

#### § 524.1600b Nystatin, neomycin, thioestrepton, and triamcinolone acetone ophthalmic ointment.

(a) *Specifications.* Each cubic centimeter of ointment contains: 100,000 units of nystatin, neomycin sulfate equivalent to 2.5 milligrams of neomycin base, 2,500 units of thioestrepton, and 1.0 milligram of triamcinolone acetone.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for ophthalmic use as an anti-inflammatory, antipruritic, antifungal (*Candida albicans*), and antibacterial ointment for local therapy in keratitis and conjunctivitis in cats and dogs and for infectious keratoconjunctivitis (pink eye) in cattle.

(2) It is to be administered as follows:

(i) For conjunctivitis and keratitis: Apply one drop of ointment to the affected eye(s) two or three times daily. Treatment may be continued for up to 2 weeks if necessary.

(ii) For bovine infectious keratoconjunctivitis: Apply small line of ointment to the affected eye(s) once daily. Treatment may be continued for up to 2 weeks if necessary.

(iii) Frequency of administration is dependent on the severity of the condition. For mild inflammations, applications may range from once daily to once a week; for severe conditions the drug may be applied as often as two to three times daily. Frequency of treatment may be decreased as improvement occurs.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]